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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,318	05/31/2001	David Fikstad	WP 2001.00	1207

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
12/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/871,318	FIKSTAD ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5,14,17-19 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5, 14, 17, 18,19 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 3-5, 17, 22-24 and 28-30 remain as the BPAI affirmed the examiners rejection of these claims in the decision mailed 8/28/2008. Thus, these claims should be cancelled by applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 18, 19 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ebert et al (USPN 5,662,925 hereafter '925) in view of Cormier (USPN 6,203,817 hereafter '817) and Ke et al (USPN 6,323,232 hereafter '232), for the reasons set forth in the BPAI decision mailed 10/27/2008 and reiterated herein.

The ‘925 patent discloses a transdermal delivery device comprising an backing layer, an active agent, a reservoir, a peel seal disc, a heat seal, an adhesive overlay and a removable release liner (Figure 1, col. 2, lin. 60 to col. 3, lin 10). The reference is however silent to the inclusion of lasofoxifene. It would have been well within the level of skill in the art to include a transdermal lasofoxifene formulation into the device as shown in the '817 and ‘232 patent.

The ‘817 patent discloses a transdermal formulation comprising an adhesive matrix reservoir (abstract). The transdermal attached to the skin and comprises an adhesive overlay (part 22), a backing layer attached to the overlay (part 14), a reservoir under said backing layer (part 12), an optional active agent-permeable layer under said reservoir, a further disc layer (part 24), and a release liner (not pictured) (column 9, line 21-60). The device is further sealed to prevent leakage (column 9, line 30-35). The transdermal device further comprises permeation enhancers such as ethanol or propylene glycol (column 10, lines 5-29; examples). The transdermal comprises a gel matrix comprising gelling agents such as hydroxypropylcellulose and colloidal silicone dioxide (column 10, lines 22-39). The transdermal formulation delivers various active agents including antiestrogen and antiosteoporotic agents such as tamoxifen and raloxifene (column 7, lines 66-68; column 8, lines 9-12). The reference however lacks a disclosure of lasofoxifene, a similar antiestrogen agent.

The ‘232 patent discloses a combination of active agents in a transdermal comprising including lasofoxifene and other estrogen agonists/antagonist (claim 1). Among other agents used in the combination therapy are droloxifene, raloxifene and

tamoxifen (column 6, lines 35-40). The transdermal formulation comprises propylene glycol and is sterile (column 37, lines 38-52). These agents are identical to those preferred in the '817 patent and act as functional equivalents of each other. It would have been obvious to include the lasofoxifene of the '232 patent into the device of the '817 patent since they comprise similar components, and are within the same field of endeavor.

It would have been obvious to a person of ordinary skill in the art to combine the device of '925 patent with the transdermal administration of lasofoxifene shown in the '817 and '232 patents since Ebert discloses that the device is useful for the administration of a variety of agents including estradiols (col. 4, lin. 20). This combination thus amounts to the predictable use of prior art elements according to their established functions. *See KSR*, 127 S Ct. at 1740.

Response to Amendment

The Affidavit under 37 CFR 1.132 filed 10/27/08 is insufficient to overcome the rejection of claims 14, 18, 19, and 25-27 based upon 35 USC 103(a) as set forth in the last Office action because: the Declaration is an opinion Affidavit by an unrelated party. The opinion affidavit argues that same points put forth in previous responses to prior art rejections. Lasofoxifene is of a different chemical structure than that of the other listed compounds in the Ke and Cormier patents. However as stated in the Board Decision dated 8/27/08 the Ke patent provides transdermal formulation for lasofoxifene (claim 1), raloxifene or tamoxifen (claims, col. 3, lin. 49). Cormier provides transdermal

formulation for tamoxifen and raloxifene, establishing that though difficult, the artisan of ordinary skill is able to include differing active compounds within a similar carrier formulation despite differences in chemical structure. Their functions and intents remain the same and as such it remains obvious. For these reasons the claims remain obvious.

Response to Arguments

Applicant's arguments filed 10/27/08 have been fully considered but they are not persuasive. Applicant argues that:

It would not have been obvious to combine the combination of the Cormier and Ke patents into the device of the Ebert patent.

Applicant argues that it would have been obvious to combine the Ebert device with the transdermal formulation of the Cormier and Ke patents.

However as stated in the Board decision dated 10/27/08, it would have been obvious since Cormier and Ke patent establish the level of skill in the art regarding transdermal lasofoxifene formulations, and the Ebert patent simply provides a device that is suggest skill similar compounds (estradiols). The substitution of one drug for another drug for the same use is obvious given the patents teach that various drugs may be employed in the medical devices, in combination and/or interchangeably.

Applicant argues that the presumption that the drugs are in the same pharmacological class and thus their interchangability is incorrect.

This is not found persuasive because it is not critical that the compounds have a similar structure, as asserted by Appellant, but may be related in behavior. Combining

prior art elements according to known methods to yield predictable results and in this case substituting one estrogen drug for another would be predictable as placing various drugs interchangeable on an adhesive matrix is well known and predictable, as the art shows that various drugs may be included on such a membrane. While the argument provides assertions and opinion affidavit that the compounds (drugs) are different, there is nothing to support these assertions that these drugs could not be substituted for another in the methods of making the device as claimed. Some evidence or sound reasoning needs to be provided to rebut the prior art showing that drugs can be substituted in the making of such a device. There is nothing to indicate that the different structures of the drugs would provide unpredictability of including it on a membrane as in the claimed methods. Furthermore, obviousness does not require absolute predictability. This combination is merely a combination of familiar elements according to known methods and does not yet unpredictable results. See *KSR Int'l Co v Teleflex Inc.*, 127 S.Ct 1727, 1739. For these reasons that those set forth in the board decision dated 08/27/08 the claims remain rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618